

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF
NORTHERN DIVISION

Case: 1:24-cv-12000
Judge: Ludington, Thomas L.
MJ: Morris, Patricia T.
Filed: 07-30-2024

Patrick-Joseph: Groulx

Plaintiff/Prosecutor

JURY TRIAL IS DEMANDED PURSUANT
TO THE SEVENTH AMENDMENT OF THE
UNITED STATES CONSTITUTION

Vs.

Takeda Pharmaceutical Company aka BioLife Plasma Services, Takeda Oncology, Takeda Canada, Takeda U.K., Takeda France, TiGenix, Nimbus Lakshmi, Maverick Therapeutics, TAP Pharmaceuticals, Takeda Science Foundation, Baxter BioScience Manufacturing Sarl, PVP Biologics, Shire Pharmaceutical Holdings Ireland, Takeda Bio Development Center Limited, Takeda Farmacéutica Brasil, Takeda Manufacturing U.S.A., Takeda (China) Holdings Co., Adaptate Biotherapeutics, Takeda Pharma Vertrieb, Shire Acquisitions Investments Ireland Designated Activity Company, Takeda Nederland, Takeda America Holdings, Takeda Italia, Takeda Pharmaceuticals Asia Private Limited, Nycomed Austria, Takeda Healthcare Philippines, A-Digital, Takeda Belgium, Takeda Israel, Takeda Europe Holdings, Pharma International Insurance, Takeda Pharmaceuticals Korea Co., Nycomed Pharmaceuticals, Takeda Farmaceuticos Portugal, Nycomed SICAR, Takeda Italia Farmaceutici, Tianjin Takeda Pharmaceuticals Co., Takeda Development Centre Europe, Nycomed Christiaens, Takeda Pharma, Plasmapunkt Favoriten, Takeda Dunboyne Biologics Limited, Takeda Pharmaceuticals International, TAP Finance, Takeda Globalresearch & Development Center, PT. Takeda Indonesia, Plasmaspendedienst, Plasmaspendezentrum Donaustadt, Takeda, and Vascular Plazma

Baxter Healthcare Corporation aka BioLife Plasma Services, Welch Allyn, Liko, Milacron, Hill-Rom Holdings, Mortara Instrument, Trumpf Medical Systems, Hill Rom, Epiphany Cardiography Products, Comfort Holdings, Hill-Rom de Mexico, Eagle Acquisition Sub, Connecta Soft, Welch Allyn Holdings, Huntersville Insurance Company, Hillrom Investment Holdings, Vantive US Healthcare, Baxter Corporation, Laboratorios Baxter, Baxter India Private Limited, Baxter, Gambro, Baxter Hospitalar, Baxter Medical AB, Baxter Healthcare Corporation of Puerto Rico, Baxter Belgium, Cheetah Medical, Baxter Deutschland, Synovis Life Technologies, Baxter Pharmaceutical Solutions, Gambro Lundia AB, Baxter Healthcare Pty, Baxter Corporation Englewood, Synovis Micro Companies Alliance, Baxter Ecuador, Gambro Dasco Spa, Bieffe Medital, Baxter AG, toSense, Baxter Médico-Farmacéutica, Baxter Pharmaceuticals India Pvt, Baxter Limited, Claris Injectables Limited, Baxter (Malta) Holding, Vantive Health, Gambro, Baxter BioSurgery, Gambro Renal Products, RTS Americas, Sapa Prodotti Plastici Sagl, Baxter World Trade Corporation, Baxter Incorporated, Gambro Renal Products, Baxter Deutschland Holding, Baxter Productos Medicos, Wound Care Technologies, Baxter Oy, Baxter Healthcare Limited, Baxter Argentina, Baxter Polska, and Baxter Pacific Investments

BioLife Plasma Services LP,

DEFENDANTS.

COMPLAINT

I. PARTIES OF THE COMPLAINT AND THEIR CONTACT INFORMATION

- A. Patrick-Joseph Groulx is the Plaintiff and the Prosecutor who resides in Saginaw Michigan at 2070 Houlihan Road with a contact number of 989 860-2550 and an email of mr.288074@yahoo.com.
- B. Takeda Pharmaceutical Company aka BioLife Plasma Services is located at 75 Sidney Street Cambridge, MA 02139 and is incorporated under the laws of Delaware and has a registered agent known as the Corporation Company located at 40600 Ann Arbor Road E STE 201, Plymouth MI 48170
- C. Baxter Healthcare Corporation aka BioLife Plasma Services is located at 1 Baxter Parkway, Deerfield, IL 60015 and is incorporated under the laws of Delaware and has a registered agent known as the Corporation Company located at 40600 Ann Arbor Road E STE 201, Plymouth MI 48170
- D. BioLife Plasma Services LP has a headquarters located at 1200 Lakeside Dr, Deerfield, Illinois 60015 and is incorporated under the laws of Delaware and has a registered agent known as the Corporation Company located at 40600 Ann Arbor Road E STE 201, Plymouth MI 48170

JURISDICTION AND VENUE

Jurisdiction and venue are proper in this Court pursuant to 28 U.S.C. § 1332 and § 1391 because the amount in controversy exceeds \$75,000.

II. TERMS OF THE COMPLAINT

- a. If Defendants fail to Object to any of the terms inscribed here, defendants lose their right to argue the terms and lose their right to argue any term not objected to in an appeal.
- b. Every Objection must be separate from the Answer; an Objection is not an answer to a complaint.

- c. Every Objection for a term is a separate objection, 2 or more terms cannot be combined in a single objection, each term being objected to must be a different filing.
- d. Failure to Object to any term will leave a door open for a motion for an order reflecting the terms to be enforced in this suit.
- e. The Plaintiff, the Court and the Judge and/or Magistrate Judge are not bound to these terms.
- f. Defendant cannot file a summary disposition unless it is used to fix a defective document.
- g. Defendants cannot file a motion to dismiss.
- h. Plaintiff will have the right to amend his Complaint as needed to the 12th time.
- i. Defendants are not allowed to Sanction Plaintiff.
- j. Defendants cannot file a motion for Sanctions.
- k. Defendants cannot deem this action as frivolous.
- l. Plaintiff only has to prove injury, harm or loss, nothing more and nothing less.

III. NATURE OF THE ACTION

I. INTRODUCTION

This is an action for fraudulently taking over 880 ml of plasma from Plaintiff without compensation and taking over 880 ml of plasma endangered Plaintiff's wellbeing which had the potential to kill Plaintiff when taking over 880 ml of plasma from a person such as the Plaintiff

II. FACTUAL BACKGROUND

According to the Code of Federal Regulations Title 21, Section 640.63, individuals who weigh 175 pounds or more may donate plasma up to two times in a seven-day period, with at least 48 hours between donations. However, the total volume of plasma collected in a single donation may not exceed 880 milliliters.

On January 12, 2023, at G3559 Miller Rd, Flint, MI 48507, Defendant-C, Bio Life Plasma Services took over 880 ml of plasma from Plaintiff Patrick-Joseph Groulx without compensation. (See Exhibit-A, B and C)

On January 14, 2023, at G3559 Miller Rd, Flint, MI 48507, Defendant-C, Bio Life Plasma Services took over 880 ml of plasma from Plaintiff Patrick-Joseph Groulx without compensation. (See Exhibit-A, B and C)

On January 19, 2023, at G3559 Miller Rd, Flint, MI 48507, Defendant-C, Bio Life Plasma Services took over 880 ml of plasma from Plaintiff Patrick-Joseph Groulx without compensation. (See Exhibit-A, B and C)

On January 21, 2023, at G3559 Miller Rd, Flint, MI 48507, Defendant-C, Bio Life Plasma Services took over 880 ml of plasma from Plaintiff Patrick-Joseph Groulx without compensation. (See Exhibit-A, B and C)

On January 26, 2023, at G3559 Miller Rd, Flint, MI 48507, Defendant-C, Bio Life Plasma Services took over 880 ml of plasma from Plaintiff Patrick-Joseph Groulx without compensation. (See Exhibit-A, B and C)

On January 28, 2023, at G3559 Miller Rd, Flint, MI 48507, Defendant-C, Bio Life Plasma Services took over 880 ml of plasma from Plaintiff Patrick-Joseph Groulx without compensation. (See Exhibit-A, B and C)

On February 2, 2023, at G3559 Miller Rd, Flint, MI 48507, Defendant-C, Bio Life Plasma Services took over 880 ml of plasma from Plaintiff Patrick-Joseph Groulx without compensation. (See Exhibit-A, B and C)

On February 4, 2023, at G3559 Miller Rd, Flint, MI 48507, Defendant-C, Bio Life Plasma Services took over 880 ml of plasma from Plaintiff Patrick-Joseph Groulx without compensation. (See Exhibit-A, B and C)

Plaintiff alleges that Defendant-C fraudulently took over 880 ml of plasma from him while not providing any compensation and causing health issues. (See Exhibit-A, B and C)

DEFENDANT A and B

Defendant-A and B are the parents of Defendant-C which are all equally to be sued civilly

Plaintiff's RESEARCH AND FINDINGS

Plaintiff finds it wrong to take over 880 ml of plasma from a person. This is because plasma is a vital part of the human body, and taking too much can lead to serious health problems.

Plasma is the liquid portion of blood that carries nutrients and oxygen to the cells and removes waste products. It also contains antibodies, which help the body fight infection.

Taking too much plasma can lead to a number of problems, including:

Dehydration, Fatigue, Dizziness, Lightheadedness, Headache, Nausea, Migraine,
Vomiting, Muscle cramps, Low blood pressure, Shock, and Death,

In severe cases, taking too much plasma can lead to death.

Plaintiff believes that taking over 880 ml of plasma from a person is wrong because it can put the person's health at risk

Plaintiff is entitled to a full Relief

Plaintiff is entitled \$80,000,000,000.00 (Eighty Billion dollars) from Defendant -A (See Exhibit-D); \$800,000,000 (Eight Hundred Million) from Defendant-B (See Exhibit-E) and \$8,000,000.00 (Eight Million Dollars) from Defendant-C (See Exhibit-F) for negligence, violating federal law, and for endangering Plaintiff's wellbeing which could of led to a serious injury and/or death.

III. CIVIL CLAIM

1. Plaintiff incorporates by reference the civil claim in the proceeding paragraphs:

COUNT I

DEFENDANT-A'S SUBSIDIARY BIOLIFE FRAUDULENT NONCOMPLIANCE WITH TITLE 21, SECTION 640.63 OF THE CODE OF FEDERAL REGULATIONS THROUGH THE COLLECTION OF OVER 880 MILLILITERS OF PLASMA

1. DEFENDANT-A's subsidiary Biolife knowingly know that they illegally took over 880 ml of plasma from Plaintiff pursuant to Code of Federal Regulations Title 21, Section 640.63 (See Exhibits A-C and G)
2. Defendant-A and its subsidiary knowingly know the Code of Federal Regulations Title 21 Section 640.63 is publically known. (See Exhibit-G)

3. Defendant-A's subsidiary BioLife fraudulently on January 12th, 14th, 19th, 21st, 26th, and 28th of 2023 and February 2nd and 4th of 2023 at G3559 Miller Rd, Flint, MI 48507 at around 9:00 am to 12 pm. (See Exhibits A-C)
4. Defendant-A and its subsidiary BioLife knowingly know this increases health issues to Plaintiff.
5. Defendant-A's subsidiary BioLife owed Plaintiff a duty to exercise reasonable care in the collection and use of his plasma.
6. Defendant-A's subsidiary BioLife breached this duty by negligently taking over 880 ml of Plaintiffs' plasma without compensation and endangering Plaintiff's health.
7. Plaintiff DEMANDS a full and total EXTRA- ORDINARY RELIEF of \$80,000,000,000.00 (Eighty Billion dollars) from Defendant-A, civilly, severally, fraudulently, corporately, personally, strictly, and tortuously, with an annual interest rate of 13%, compounded each month with 1% from the time of filing the Summons and Complaint for personal, special and private damages and,

COUNT I

**DEFENDANT-B'S SUBSIDIARY, BIOLIFE FRAUDULENT
NONCOMPLIANCE WITH TITLE 21, SECTION 640.63 OF THE CODE OF
FEDERAL REGULATIONS THROUGH THE COLLECTION OF OVER 880
MILLILITERS OF PLASMA**

1. DEFENDANT-B's subsidiary Biolife knowingly know that they illegally took over 880 ml of plasma from Plaintiff pursuant to Code of Federal Regulations Title 21, Section 640.63. (See Exhibits A-C and G)
2. Defendant-B and its subsidiary knowingly know the Code of Federal Regulations Title 21 Section 640.63 is publically known. (See Exhibit G)
3. Defendant-B's subsidiary BioLife fraudulently on January 12th, 14th, 19th, 21st, 26th, and 28th of 2023 and February 2nd and 4th of 2023 at G3559 Miller Rd, Flint, MI 48507 at around 9:00 am to 12 pm. (See Exhibits A-C)
4. Defendant-B and its subsidiary BioLife knowingly know this increases health issues to Plaintiff.
5. Defendant-B's subsidiary BioLife owed Plaintiff a duty to exercise reasonable care in the collection and use of his plasma.

6. Defendant-B's subsidiary BioLife breached this duty by negligently taking over 880 ml of Plaintiffs' plasma without compensation and endangering Plaintiff's health.
7. Plaintiff DEMANDS a full and total EXTRA-ORDINARY RELIEF of \$800,000,000 (Eight Hundred Million) from Defendant-B civilly, severally, fraudulently, corporately, personally, strictly, and tortuously, with an annual interest rate of 13%, compounded each month with 1% from the time of filing the Summons and Complaint for personal, special and private damages and,

COUNT I

**DEFENDANT-C FRAUDULENT NONCOMPLIANCE WITH TITLE 21,
SECTION 640.63 OF THE CODE OF FEDERAL REGULATIONS THROUGH
THE COLLECTION OF OVER 880 MILLILITERS OF PLASMA**

1. DEFENDANT-C knowingly know that they illegally took over 880 ml of plasma from Plaintiff pursuant to Code of Federal Regulations Title 21, Section 640.63. (See Exhibit A-C and G)
2. Defendant-C knowingly know the Code of Federal Regulations Title 21 Section 640.63 is publically known. (See Exhibit G)
3. Defendant-C fraudulently on January 12th, 14th, 19th, 21st, 26th, and 28th of 2023 and February 2nd and 4th of 2023 at G3559 Miller Rd, Flint, MI 48507 at around 9:00 am to 12 pm. (See Exhibits A-C))
4. Defendant-C knowingly know this increases health issues to Plaintiff.
5. Defendant-C owed Plaintiff a duty to exercise reasonable care in the collection and use of his plasma.
6. Defendant-C breached this duty by negligently taking over 880 ml of Plaintiffs' plasma without compensation and endangering Plaintiff's health.
7. Plaintiff DEMANDS a full and total EXTRA-ORDINARY RELIEF of \$8,000,000.00 (Eight Million Dollars) from Defendant-C civilly, severally, corporately, punitively, personally, fraudulently, strictly, and tortuously, with an annual interest rate of 13%, compounded each month with 1% from the time of filing the Summons and Complaint for personal, special and private damages.

IV. EXTRA-ORDINARY RELIEF

A. Plaintiff DEMANDS a full and total EXTRA- ORDINARY RELIEF of \$80,000,000,000.00 (Eighty Billion dollars) from Defendant-A, civilly, severally, fraudulently, corporately, personally, strictly, and tortuously, with an annual interest rate of 13%, compounded each month with 1% from the time of filing the Summons and Complaint for personal, special and private damages

and,

B. Plaintiff DEMANDS a full and total EXTRA-ORDINARY RELIEF of \$800,000,000 (Eight Hundred Million) from Defendant-B civilly, severally, fraudulently, corporately, personally, strictly, and tortuously, with an annual interest rate of 13%, compounded each month with 1% from the time of filing the Summons and Complaint for personal, special and private damages

and,

C. Plaintiff DEMANDS a full and total EXTRA-ORDINARY RELIEF of \$8,000,000.00 (Eight Million Dollars) from Defendant-C civilly, severally, corporately, punitively, personally, fraudulently, strictly, and tortuously, with an annual interest rate of 13%, compounded each month with 1% from the time of filing the Summons and Complaint for personal, special and private damages.

Patrick-Joseph Groulx

Patrick-Joseph Groulx
2070 Houlihan Road
Saginaw Michigan [48601]
989 860-2550
mr.288074@yahoo.com

July 29, 2024
Date

*Exhibit
A
With Attachments*

AN AFFIDAVIT OF TRUTH BY Patrick-Joseph: Groulx

NOW COMES Affiant, Patrick-Joseph: Groulx with an Affidavit of Truth.

Affiant incorporates all the facts, truths and declarations in the preceding paragraphs:

- A. **I, Patrick-Joseph: Groulx** am competent for stating the matters set forth here with.
- B. **I, Patrick-Joseph: Groulx** have personal knowledge concerning the facts stated herein.
- C. All the facts stated herein are true, correct, complete, and certain, not misleading, admissible as evidence, and if stating **I, Me, Myself**, and One Patrick-Joseph: Groulx shall so state:

On January 12, 2023, Takeda Pharmaceuticals International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

On January 14, 2023, Takeda Pharmaceuticals International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

On January 19, 2023, Takeda Pharmaceuticals International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

On January 21, 2023, Takeda Pharmaceuticals International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

On January 26, 2023, Takeda Pharmaceuticals International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

On January 28, 2023, Takeda Pharmaceuticals International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

On February 2, 2023, Takeda Pharmaceuticals International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

On February 4, 2023, Takeda Pharmaceuticals International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

D. If any living soul has information that will controvert and overcome this Declaration, since this a commercial matter, please advise me IN WRITING by DECLARATION/AFFIDAVIT FORM, under your unlimited commercial liability, including but not limited to the pains and penalties of perjury, within 28 days providing me with your counter Declaration/Affidavit, proving with particularity by stating all requisite actual evidentiary fact(s) and all requisite actual law, and not merely the ultimate facts and law conclusions that this affidavit by Declaration is substantially and materially my or the fiction's status and factual declaration.

E. Your silence stands as consent, and tacit approval, for the factual declarations here being established as fact as a law matter and this affidavit by Declaration will stand as evidence against you.

Plain Statement of Facts

I declare that the statements above are true to the best of my information, knowledge, and belief.

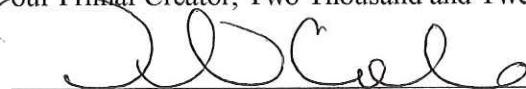

Patrick-Joseph Groulx
2070 Houlihan Road
Saginaw Michigan 48601
989 860-2550

7-22-2024
Date

JURAT

SAGINAW COUNTY)
)
MICHIGAN STATE)

Subscribed and affirmed before me this 22nd day for the July month in the year of our Primal Creator, Two Thousand and Twenty-Four(2024), A.D.

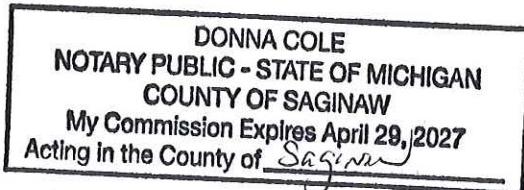


Notary

100 S. Michigan Ave Seal
Address of notary

Apr. 1 29, 2027

My notary expires



January 14, 2023

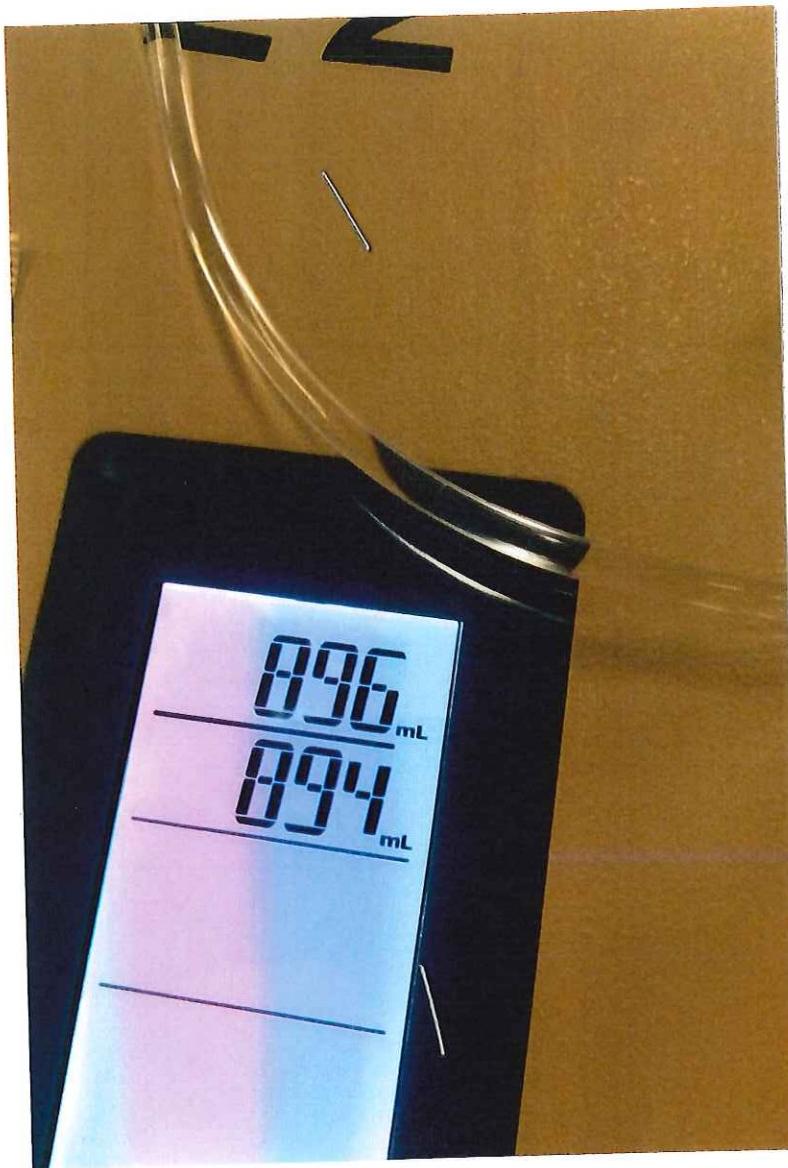
Attachment A
to Exhibit
A



What this
means is that
more plasma
is being donated

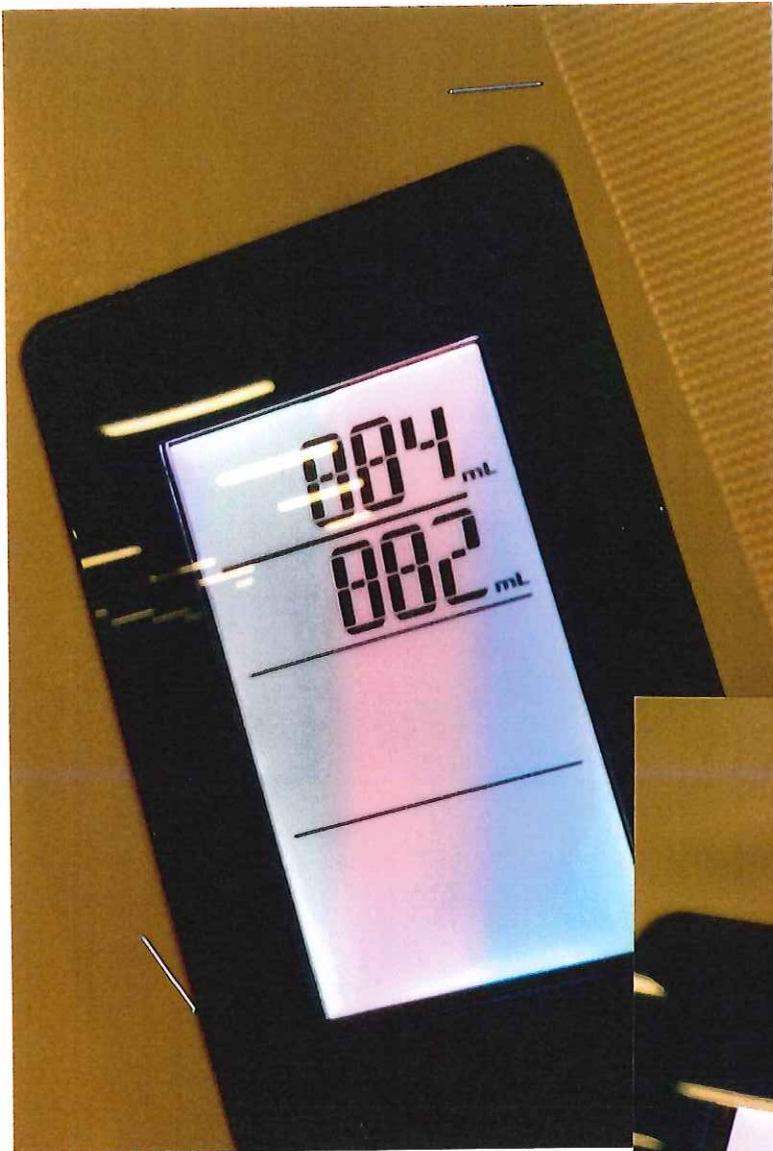
January 26, 2023

Attachment-B
to Exhibit-A



January 28th of 2023

Attachment
to Exhibit A



February 4, 2024
↓



AN AFFIDAVIT OF TRUTH BY Patrick-Joseph: Groulx

*Exhibit
B
with
Attachments*

NOW COMES Affiant, Patrick-Joseph: Groulx with an Affidavit of Truth.

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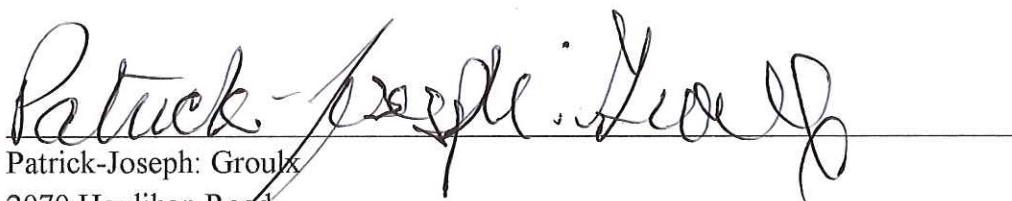
On February 2, 2023, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

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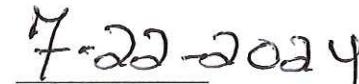
- D. If any living soul has information that will controvert and overcome this Declaration, since this a commercial matter, please advise me IN WRITING by DECLARATION/AFFIDAVIT FORM, under your unlimited commercial liability, including but not limited to the pains and penalties of perjury, within 28 days providing me with your counter Declaration/Affidavit, proving with particularity by stating all requisite actual evidentiary fact(s) and all requisite actual law, and not merely the ultimate facts and law conclusions that this affidavit by Declaration is substantially and materially my or the fiction's status and factual declaration.
- E. Your silence stands as consent, and tacit approval, for the factual declarations here being established as fact as a law matter and this affidavit by Declaration will stand as evidence against you.

Plain Statement of Facts

I declare that the statements above are true to the best of my information, knowledge, and belief.



Patrick-Joseph Groulx
2070 Houlihan Road
Saginaw Michigan 48601
989 860-2550

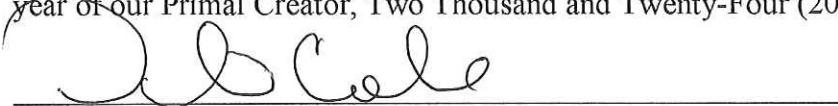


Date

JURAT

SAGINAW COUNTY)
)
MICHIGAN STATE)

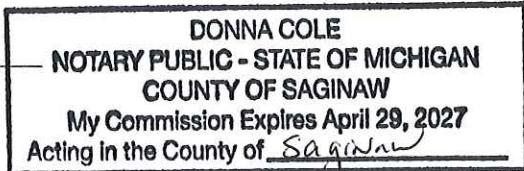
Subscribed and affirmed before me this 22nd day for the July month in the
year of our Primal Creator, Two Thousand and Twenty-Four (2024), A.D.



Notary

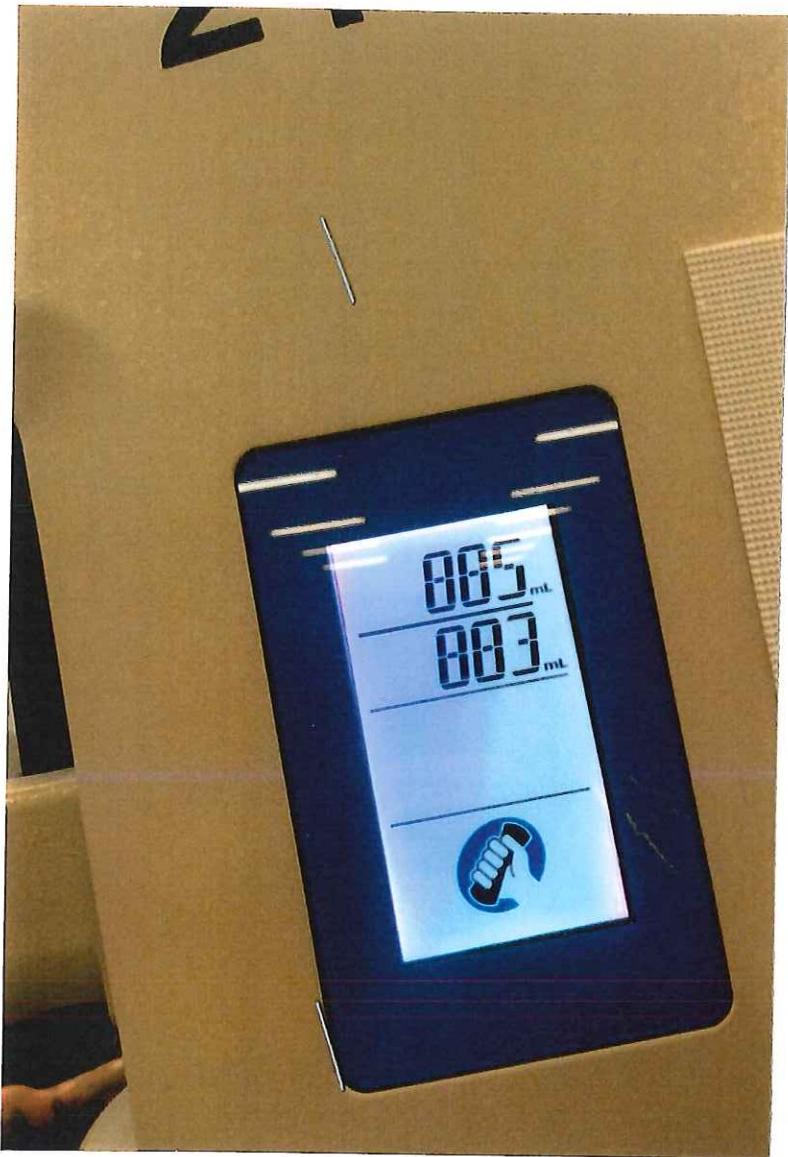
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Address of notary

Apr. 1 29, 2027
My notary expires



January 14, 2023

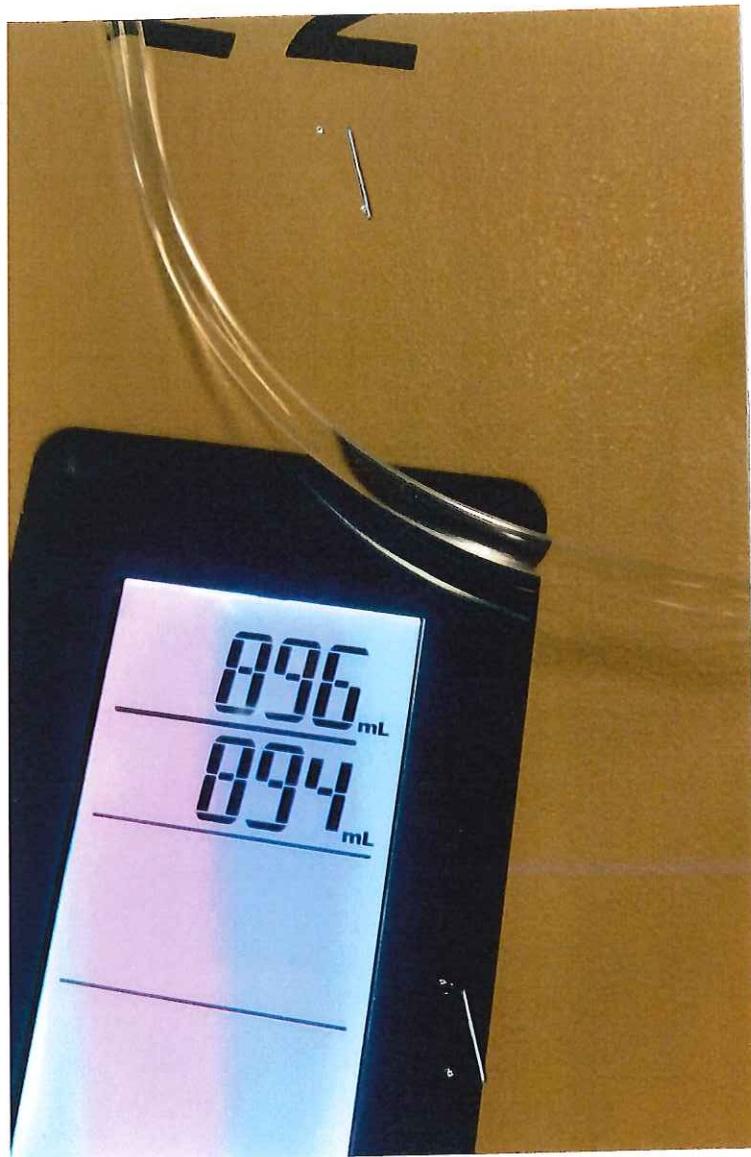
Attachment A
to Exhibit B



what the Icon means is more plasma being donated

January 26, 2023

Attachments
To Exhibits A & B



February 2, 2023

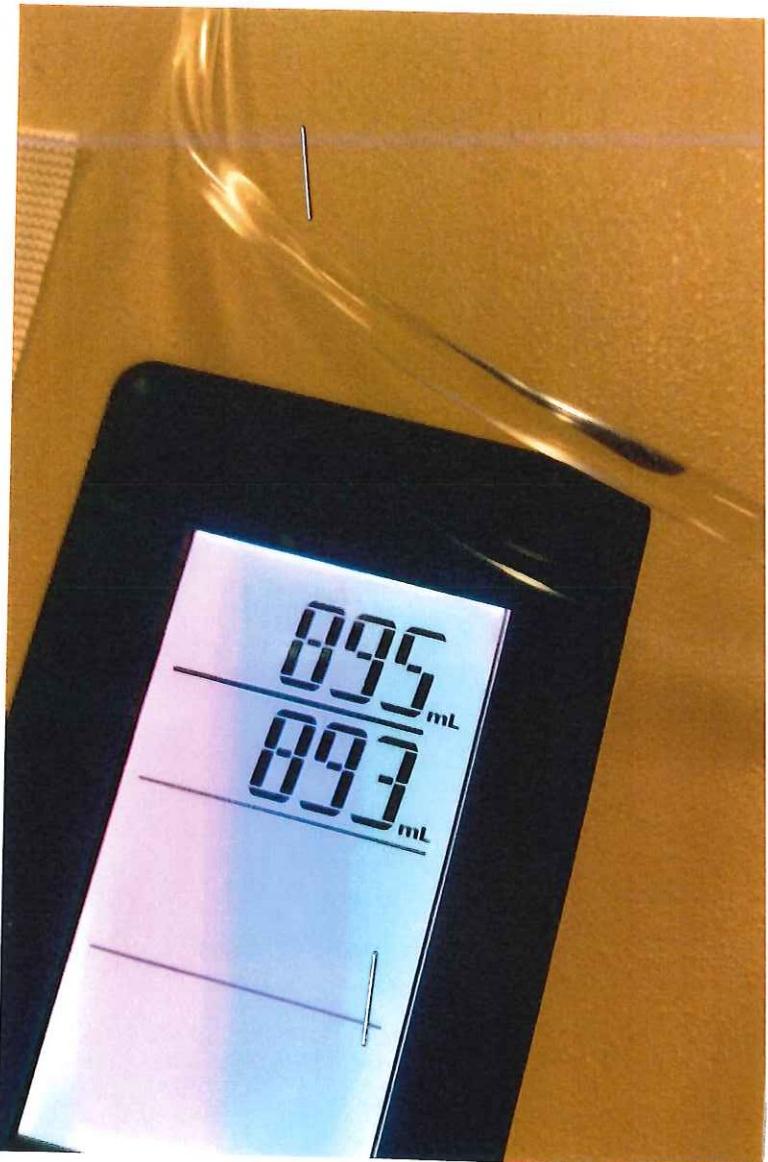


Exhibit C with Attachments

AN AFFIDAVIT OF TRUTH BY Patrick-Joseph: Groulx

NOW COMES Affiant, Patrick-Joseph: Groulx with an Affidavit of Truth.

Affiant incorporates all the facts, truths and declarations in the preceding paragraphs:

- A. **I, Patrick-Joseph: Groulx** am competent for stating the matters set forth here with.
- B. **I, Patrick-Joseph: Groulx** have personal knowledge concerning the facts stated herein.
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On February 2, 2023, Baxter International's subsidiary, BioLife took over 880 ml of plasma from me, without proper compensation and endangered my wellbeing.

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I declare that the statements above are true to the best of my information, knowledge, and belief.

Patrick-Joseph Groulx
2070 Houlihan Road
Saginaw Michigan 48601
989 860-2550

7-22-2024
Date

JURAT

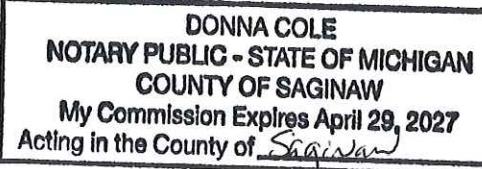
SAGINAW COUNTY)
)
MICHIGAN STATE)

Subscribed and affirmed before me this 22nd day for the July month in the year of
our Primal Creator, Two Thousand and Twenty-Four (2024), A.D.

Donna Cole
Notary

100 S. Michigan Seal
Address of notary

April 29, 2027
My notary expires



January 28, 2023

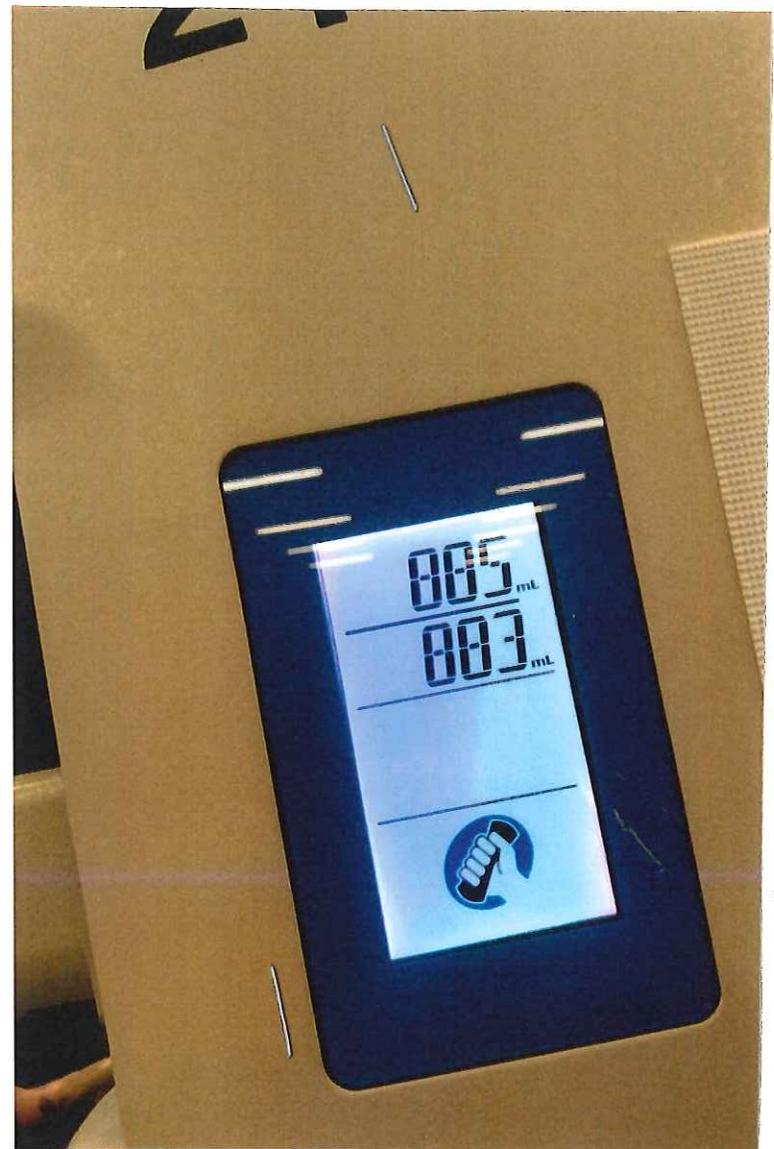
Attachment C
To Exhibit B



February 9, 2023



January 14, 2023

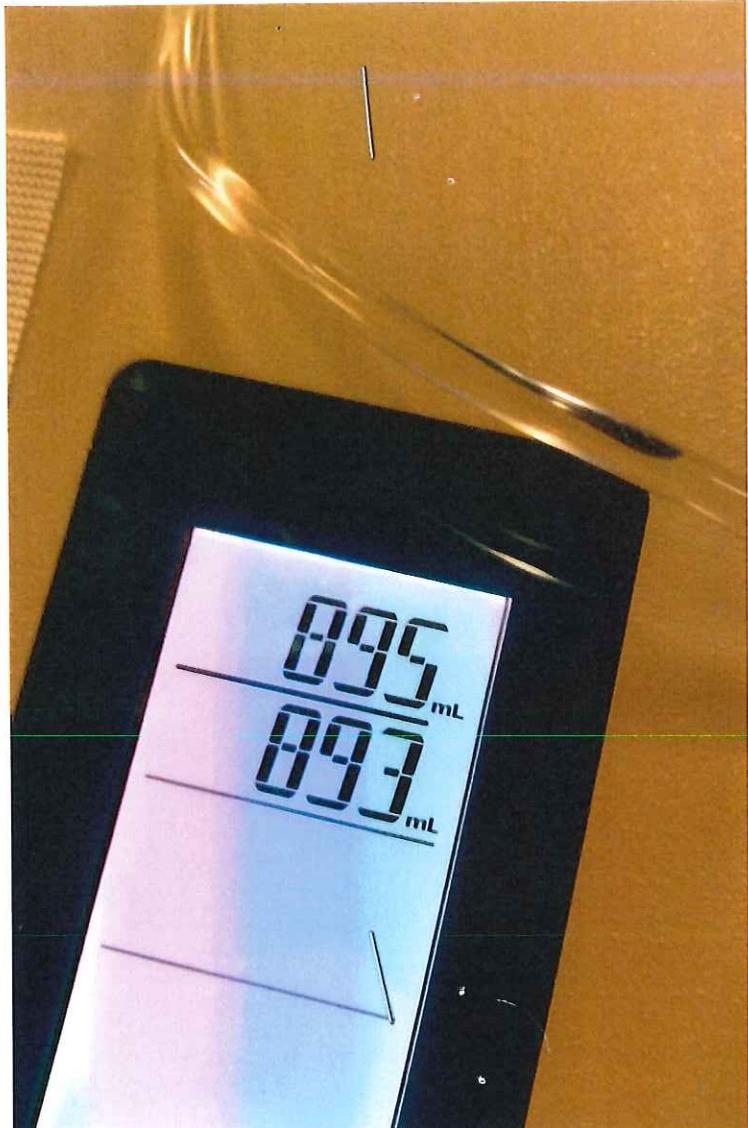
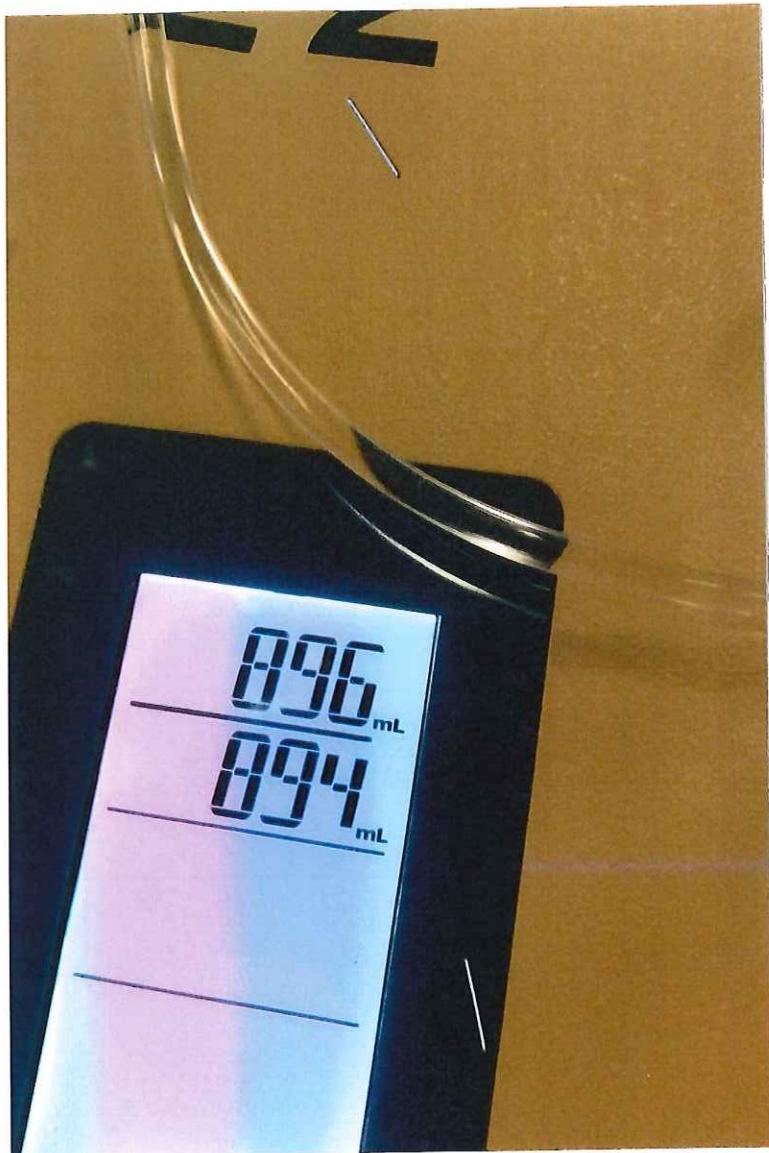


Attachment A
To Exhibit C

What the icon
means is that
more plasma
being donated

January 26, 2023

Attachment -B
TO Exhibit -C



January 28, 2023

Attachment - C
to Exhibit C



February 4, 2023



NOTICE OF INTENT AND DEMAND

Patrick-Joseph: Groulx
2070 Houlihan Road
Saginaw Michigan [48601]
mr.288074@yahoo.com
989 860-2550

E. Shabot

July 16, 2023

Takeda Pharmaceuticals U.S.A., Inc. aka BIOLIFE
Attn: Legal Department
95 Hayden Avenue,
Lexington, MA 02421

Legal Department for Takeda Pharmaceuticals,

I am writing you this notice of intention and demand that you pay me \$1,000,000,000.00 (One Billion Dollars) within 28 days of the Notice date or I will file a suit against you in Federal Court for your subsidiary BIOLIFE taking out over 880 ml of plasma from me which is a violation of federal law which will include negligence and fraud with a punitive tort. If you do not pay me within 28 days of date of this notice I will sue you for a total of 80 billion dollars for every day your subsidiary BIOLIFE took over 880 milliliters of Plasma from me, in which you agree is a proper relief of judgement against yourself.

Demanding One billion dollars is just like asking \$1.00 from someone who has \$300.00

This NOTICE is dated 10 days in advance for your convenience.

In alternative you can pay me \$640,000.00 that is \$80k for each day; this offer ends July 30, 2023.

Failure to compensate me is a negative gesture and your inactivity to compensate me gesture that you want me to sue you in federal court for \$80,000,000,000.00 (Eighty Billion Dollars which you deem is the proper compensation as a judgement against yourself

To pay me the amount demanded you must deposit the amount in my Huntington Bank Account using this account number: 02381978707 and a Routing Number: 072403473 with the name PATRICK GROULX and paying me this demanded amount will show a positive gesture of good faith and I will not sue Takeda Pharmaceuticals for the allegations as stated in this NOTICE.

/s/ Patrick-Joseph: Groulx

Patrick-Joseph: Groulx

Date: July 6, 2023

PROOF OF SERVICE

Patrick-Joseph: Groulx certifies that he mailed Takeda Pharmaceuticals U.S.A., Inc. at 95 Hayden Avenue, Lexington, MA 02421 this notice on July 6, 2023 using first class mail through the USPS.

/s/ Patrick-Joseph: Groulx

Patrick-Joseph: Groulx

Date: July 6, 2023

NOTICE OF INTENT AND DEMAND

Patrick-Joseph: Groulx
2070 Houlihan Road
Saginaw Michigan [48601]
mr.288074@yahoo.com
989 860-2550

Evidence
E

July 16, 2023

Baxter International aka BioLife
Attn: Legal Department
1 Baxter Parkway
Deerfield, IL 60015

Legal Department for Baxter International

I am writing you this notice of intention and demand that you pay me \$100,000,000.00 (One Hundred Million Dollars) within 28 days of the Notice date or I will file a suit against you in Federal Court for your subsidiary BIOLIFE taking out over 880 ml of plasma from me which is a violation of federal law which will include negligence and fraud with a punitive tort. If you do not pay me within 28 days of date of this notice I will sue you for a total of \$800,000,000.00 dollars for every day your subsidiary BIOLIFE took over 880 milliliters of Plasma from me, in which you agree is a proper relief of judgement against yourself.

Demanding One Hundred Million dollars is just like asking \$10.00 from someone who has \$230.00

This NOTICE is dated 10 days in advance for your convenience.

In alternative you can pay me \$640,000.00 that is \$80k for each day; this offer ends July 30, 2023.

To pay me the amount demanded you must deposit the amount in my Huntington Bank Account using this account number: 02381978707 and a Routing Number: 072403473 with the name PATRICK GROULX and paying me this demanded amount will show a positive gesture of good faith and I will not sue you for the allegations as stated in this NOTICE.

/s/ Patrick-Joseph: Groulx
Patrick-Joseph: Groulx

Date: July 6, 2023

PROOF OF SERVICE

Patrick-Joseph: Groulx certifies that he mailed Baxter International, at 1 Baxter Parkway Deerfield, IL 60015 this notice using first class mail through USPS.

/s/ Patrick-Joseph: Groulx
Patrick-Joseph: Groulx

Date: July 6, 2023

NOTICE OF INTENT AND DEMAND

Patrick-Joseph: Groulx
2070 Houlihan Road
Saginaw Michigan [48601]
mr.288074@yahoo.com
989 860-2550

Exhibit F

July 16, 2023

BioLife
Attn: Legal Department
1200 Lakeside Dr,
Deerfield, Illinois, 60015,

Legal Department for Biolife

I am writing you this notice of intention and demand that you pay \$500,000.00 (Five Hundred Thousand Dollars) within 28 days of the date of this NOTICE or I will file a suit against you in Federal Court for taking out over 880 ml of plasma from me which is a violation of federal law. If you do not pay me within 28 days of date of this notice I will sue you for fraud and negligence with a punitive tort for a total of \$8,000,000.00 Million dollars for every day you took over 880 milliliters of Plasma from me, in which you agree is a proper relief of judgement against yourself.

Demanding Five Hundred Thousand dollars is just like asking \$0.50 from someone who has \$100.00

This NOTICE is dated 10 days in advance for your convenience.

In alternative you can pay me \$80,000.00 that is \$10k for each day; this offer ends July 30, 2023.

To pay me the amount demanded you must deposit the amount in my Huntington Bank Account using this account number: 02381978707 and a Routing Number: 072403473 with the name PATRICK GROULX and paying me this demanded amount will show a positive gesture of good faith and I will not sue you for the allegations as stated in this NOTICE.

/s/ Patrick-Joseph: Groulx
Patrick-Joseph: Groulx

Date: July 6, 2023

PROOF OF SERVICE

Patrick-Joseph: Groulx certifies that he mailed BioLIfe. at 1200 Lakeside Dr, Deerfield, Illinois, 60015 this notice on July 6, 2023 using 1st class mail through the USPS.

/s/ Patrick-Joseph: Groulx
Patrick-Joseph: Groulx

Date: July 6, 2023

Exhibit
G

Food and Drug Administration, HHS

§ 640.63

being collected, and red blood cells are being returned to the donor.

§ 640.63 Suitability of donor.

(a) *Method of determining.* The suitability of a donor for Source Plasma shall be determined by a qualified licensed physician or by persons under his supervision and trained in determining donor suitability. Such determination shall be made on the day of collection from the donor by means of a medical history, tests, and such physical examination as appears necessary to the qualified licensed physician.

(b) *Initial medical examinations.* (1) Each donor shall be examined by a qualified licensed physician on the day of the first donation or no more than 1 week before the first donation and at subsequent intervals of no longer than 1 year.

(2)(i) A donor who is to be immunized for the production of high-titer plasma shall be examined by a qualified licensed physician. The medical examination shall be performed within no more than 1 week before the first immunization injection. The medical examination for plasmapheresis need not be repeated, if the first donation occurs within 3 weeks after the first injection.

(ii) A donor who is an active participant in a plasmapheresis program, and has been examined in accordance with paragraph (b)(1) of this section, need not be reexamined before immunization for the production of high-titer plasma.

(3) Each donor shall be certified to be in good health by the examining physician. The certification of good health shall be on a form supplied by the licensed establishment and shall indicate that the certification applies to the suitability of the individual to be a plasmapheresis donor and, when applicable, an immunized donor.

(c) *Qualification of donor.* Donors shall be in good health on the day of donation, as indicated in part by:

(1) Normal temperature;

(2) Demonstration that systolic and diastolic blood pressures are within normal limits, unless the examining physician is satisfied that an individual with blood pressures outside these limits is an otherwise qualified

donor under the provisions of this section;

(3) A blood hemoglobin level of no less than 12.5 grams of hemoglobin per 100 milliliters of blood;

(4) A normal pulse rate;

(5) A total serum protein of no less than 6.0 grams per 100 milliliters of serum;

(6) Weight, which shall be at least 110 pounds;

(7) Freedom from acute respiratory diseases;

(8) Freedom from any infectious skin disease at the site of phlebotomy and from any such disease generalized to such an extent as to create a risk of contamination of the plasma;

(9) Freedom from any disease, other than malaria, transmissible by blood transfusion, insofar as can be determined by history and examinations indicated in this section;

(10) Freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics;

(11) Freedom from a history of viral hepatitis;

(12) Freedom from a history of close contact within six months of donation with an individual having viral hepatitis;

(13) Freedom from a history of having received, within six months, human blood or any derivative of human blood which the Food and Drug Administration has advised the licensed establishment is a possible source of viral hepatitis, except for specific immunization performed in accordance with § 640.66 of this part.

(d) *General.* Any donor who, in the opinion of the interviewer, appears to be under the influence of any drug, alcohol, or for any reason does not appear to be providing reliable answers to medical history questions, shall not be considered a suitable donor.

(e) *Failure to return red blood cells.* Any donor who has not had the red blood cells returned from a unit of blood collected during a plasmapheresis procedure or who has been a donor of a unit of whole blood shall not be subjected to plasmapheresis for a period of 8 weeks, unless:

§ 640.64**21 CFR Ch. I (4-1-99 Edition)**

(1) The donor has been examined by a qualified licensed physician and certified by the physician to be acceptable for further plasmapheresis before expiration of the 8-week period;

(2) The donor possesses an antibody that is (i) transitory, (ii) of a highly unusual or infrequent specificity, or (iii) of an unusually high titer; and

(3) The special characteristics of the antibody and the need for plasmapheresing the donor are documented.

[38 FR 32089, Nov. 20, 1973, as amended at 41 FR 10768, Mar. 12, 1976; 43 FR 9805, Mar. 10, 1978; 43 FR 12311, Mar. 24, 1978; 46 FR 57480, Nov. 24, 1981; 50 FR 4140, Jan. 29, 1985]

§ 640.64 Collection of blood for Source Plasma.

(a) *Supervision.* All blood for the collection of Source Plasma shall be drawn from the donor by a qualified licensed physician or by persons under his supervision trained in the procedure.

(b) *Blood containers.* Blood containers and donor sets shall be pyrogen-free, sterile and identified by lot number. The amount of anticoagulant required for the quantity of blood to be collected shall be in the blood container when it is sterilized.

(c) *The anticoagulant solution.* The anticoagulant solution shall be sterile and pyrogen-free. One of the following formulas shall be used in the indicated volumes, except that a different formula may be used for plasma for manufacture into noninjectable products if prior written approval is obtained from the Director of the Center for Biologics Evaluation and Research at the time of licensing or in the form of a supplement to the Source Plasma product license.

(1) *Anticoagulant citrate dextrose solution (ACD).*

Tri-sodium citrate	22.0 grams.
(Na ₃ C ₆ H ₅ O ₇ ·2H ₂ O).	
Citric acid (C ₆ H ₅ O ₇ ·H ₂ O)	8.0 grams.
Dextrose (C ₆ H ₁₂ O ₆ ·H ₂ O)	24.5 grams.
Water for injection (U.S.P.) to	1,000 milliliters.
Volume per 100 milliliters blood	15 milliliters.

(2) *Anticoagulant citrate phosphate dextrose solution (CPD).*

Tri-sodium citrate	26.3 grams.
(Na ₃ C ₆ H ₅ O ₇ ·2H ₂ O).	
Citric acid (C ₆ H ₅ O ₇ ·H ₂ O)	3.27 grams.
Dextrose (C ₆ H ₁₂ O ₆ ·H ₂ O)	25.5 grams.

Monobasic sodium phosphate 2.22 grams.
(Na₂HPO₄·H₂O).

Water for injection (U.S.P.) to 1,000 milliliters.

Volume per 100 milliliters blood 14 milliliters.

(3) *Anticoagulant sodium citrate solution.*

Tri-sodium citrate 40 grams.

(Na₃C₆H₅O₇·2H₂O).

Water for injection (U.S.P.) to 1,000 milliliters.

Volume per 100 milliliters of blood 10 milliliters.

(d) *Donor identification.* Each unit of blood and plasma shall be so marked or identified by number or other symbol so as to relate it directly to the donor.

(e) *Prevention of contamination of the blood and plasma.* The skin of the donor at the site of phlebotomy shall be prepared thoroughly and carefully by a method that gives maximum assurance of a sterile container of blood. The blood shall be collected, the plasma separated, and the cells returned to the donor by aseptic methods in a sterile system which may be closed, or may be vented if the vent protects the blood cells and plasma against contamination.

[38 FR 32089, Nov. 20, 1973; 39 FR 13632, Apr. 16, 1974, as amended at 41 FR 10768, Mar. 12, 1976; 49 FR 23834, June 8, 1984; 50 FR 4140, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990; 59 FR 49351, Sept. 28, 1994; 63 FR 16685, Apr. 6, 1998]

§ 640.65 Plasmapheresis.

(a) *Procedure-general.* The plasmapheresis procedure is a procedure in which, during a single visit to the establishment, blood is removed from a donor, the plasma separated from the formed elements, and at least the red blood cells returned to the donor. This procedure shall be described in detail in the product license application.

(b) *Procedures-specific requirements.* The plasmapheresis procedure shall meet the following requirements:

(1)(i) A sample of blood shall be drawn from each donor on the day of the first medical examination or plasmapheresis, whichever comes first and at least every 4 months thereafter by a qualified licensed physician or by persons under his supervision and trained in such procedure. A serologic test for syphilis, a total plasma or serum protein determination, and a plasma or serum protein electrophoresis or quantitative immuno-diffusion test or an

**FDA Memorandum: Volume Limits for
Automated Collection of Source Plasma
(4 November 1992)**

Donor Weight	Plasma Volume or Weight	Collection Volume
110-149 lbs	625 mL (640 g)	690 mL (705 g)
150-174 lbs	750 mL (770 g)	825 mL (845 g)
≥ 175 lbs	800 mL (820 g)	880 mL (900 g)

CBER Donor Fatality Reporting

21 CFR 640.73 Subpart G – Source Plasma

“If a donor has a fatal reaction which, in any way, may be associated with plasmapheresis...”

- Immediate notification to CBER
- FDA can be reached 24 hours/day,
7 days/week
- Written follow-up report within 7 days

Volume Limits - Automated Collection of Source Plasma (11/4/92)

Date: 4 November 1992

From: Director, Center for Biologics Evaluation and Research

Subject: Volume Limits for Automated Collection of Source Plasma

To: All Registered Blood Establishments

The increased number of automated plasma collection devices with varying capacities for tailoring each collection to the specific donor has resulted in the existence of multiple Food and Drug Administration (FDA) approved nomograms which specify, for each piece of equipment, the maximum volume of plasma to be harvested from each donor category. Current considerations in determining the volume of plasma to be collected include gender, height, weight, hematocrit, and in some centers, the length of time in process or the number of cycles. Because multiple equipment types commonly coexist in a location, the potential for error due to application of an inappropriate nomogram is significantly increased. The use of various anticoagulant solutions, differing concentrations of the anticoagulant, and a range of anticoagulant to plasma ratios, additionally complicates some schema and creates additional opportunity for error.

The experience to date with all of the approved equipment indicates that there is no discernible impact on donor safety or product quality with the use of any of the current limits in preference to any other. Some Source Plasma manufacturers have requested and received approval for simplified nomograms. The FDA supports this type of process change which potentially improves the consistency of procedures for manufacturing and minimizes the opportunity for staff error.

To promote rapid implementation of such simplified schema, the Center for Biologics Evaluation and Research is informing all manufacturers that the following limits may be adopted without further notice. The anticoagulant volume is included in the third column below. This volume is based on a 1:16 (0.06) ratio of anticoagulant to anticoagulated-blood.

Donor Weight	Plasma Volume or Weight	Collection Volume
10-149 lbs	625 mL (640 g)	690 mL (705 g)
150-174 lbs	750 mL (770 g)	825 mL (845 g)
175 lbs & up	800 mL (820 g)	880 mL (900 g)

It has been determined that the use of this simplified nomogram does not constitute a significant change in manufacturing and, therefore, does not require advance approval of amendments to licenses. However, it should be noted that the nomogram is intended to be adopted as a complete set of limits. The simplified nomogram and the equipment manufacturer's nomogram should not be used simultaneously in the same center. Portions of the table should not be selectively applied in combination with some other system of limits. Variations will require advance approval of license amendments based on supporting documentation including evidence that the chance of error is not increased.

To monitor potential adverse reactions and ensure that no increased frequency of reactions is observed with this change in the volume of plasma collected, it is requested that any reactions observed for the first 1,000 procedures done under your license be reported to the FDA. If plasma from 1,000 donors has not been collected during the first three months after implementation of the new nomogram, please provide an interim report of any reactions occurring during the first three months. For your convenience we have provided a format for reporting of the desired information on adverse reactions.

Kathryn C. Zoon, Ph.D.

Addendum to FDA Memorandum
Suggested Format for
Experience Report On Plasma Collection Adverse Events

Automated device used for collection:

Anticoagulant used:

Anticoagulant to anticoagulated-whole blood ratio used during this collection procedure:

Weight of donor:

Height of donor:

Donor number and gender of donor:

Hematocrit prior to collection:

Total protein prior to collection:

Amount of plasma collected when reaction occurred:

Amount of anticoagulant used before reaction occurred:

Amount of saline administered before reaction (if any):

Type of reaction and severity (mild, moderate, severe, life-threatening):

Signs/symptoms of reaction:

Blood pressure at time of reaction:

Was physician notified?:

Treatment of donor:

Any operator error detected?

If yes, please provide additional details in accordance with FDA memorandum, March 20, 1991: Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood and Blood Components.

Other comments:

Submit to: Dr. Kathryn C. Zoon, Director
Center for Biologics Evaluation and Research
8800 Rockville Pike HFB-940
Bethesda, MD 20892

